12 KAR 5:020. Testing.

RELATES TO: KRS 260.775-260.845, 260.992
STATUTORY AUTHORITY: KRS 260.825(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 260.825(1) requires the Director of the Kentucky Agricultural Experiment Station to promulgate administrative regulations necessary for the effective enforcement of KRS 260.775 through 260.845 regarding milk. This administrative regulation establishes uniform standards and approved procedures and equipment for the analysis of milk components by licensed laboratories and testers.

Section 1. Laboratory Facilities and Environment. (1) A licensed laboratory's facilities shall meet the criteria established in Chapter 2.0310 of Standard Methods for the Examination of Dairy Products, 17th Edition, 2004.

(2) A licensed laboratory shall have established procedures for monitoring equipment performance and preventative maintenance. Specialized instrumentation shall be operated by the manufacturer's recommended procedures for operation and maintenance. Adequate records to document equipment performance monitoring and maintenance shall be kept. As applicable, equipment and supplies used by laboratories shall meet the criteria established in Chapter 2.0311 of Standard Methods for the Examination of Dairy Products, 17th Edition, 2004.

Section 2. Approved Testing Methods. (1) A laboratory and tester licensed by the director shall be approved for the methods of analysis routinely used for milk component testing. If the laboratory and tester are approved for an electronic method of analysis, they shall also be approved for any intralaboratory reference method used to monitor the electronic equipment.

(2) Methods of analysis used for testing milk samples for pay purposes or as reference methods shall include:

(a) Methods in Official Methods of Analysis of AOAC International, Volume II, Chapter 33, 21st, 2019;

(b) Methods in Standard Methods for the Examination of Dairy Products, 17th Edition, 2004; and

(c) Methods of analysis scientifically proven to be acceptable and approved by the director based on accuracy.

Section 3. Electronic Equipment. (1) Laboratories using electronic milk testing equipment associated with approved procedures shall maintain the following supplies and records:

(a) A thermostatically-controlled, circulatory water-bath of suitable size to maintain milk samples in a temperature range of 40-43^0 C (104-109.4^0 F). A milk sample being warmed in the water-bath shall not:

1. Remain in the water-bath in excess of forty (40) minutes prior to being tested; or
2. Be tested for payment purposes if the sample "oils off" while in the water-bath; and

(b) An approved electronic component testing instrument including:

1. All required accessories and reagents; and
2. An instrument operation manual.

(2) Control samples. A minimum of four (4) control samples of unhomogenized milk shall be analyzed daily before routine testing begins. The control samples shall cover the component ranges of samples typically analyzed with the instrument. Control samples for milk fat analysis shall be in the fat range of two (2) to six (6) percent.

(a) The control samples shall be prepared and test results determined for each component tested for pay purposes by recognized procedures or those procedures approved by the director based on accuracy.

(b) Control samples shall be physically handled in a manner to ensure their integrity and in a temperature range of 0.5-4.4^{0}C (33-40^0 F). Control samples to be stored more than seventy-two (72) hours shall be preserved with an approved preservative. Control samples shall be discarded if they appear to be churned, "oiled off," or spoiled.

(3) Daily performance checks. Written procedures shall be established to monitor electronic milk testing equipment for accuracy each day before testing begins. Minimum requirements for these procedures shall include:

(a) Zero check. Zero the machine for all components as prescribed by the instrument manufacturer. Run a single, unhomogenized milk sample through the machine at least eleven (11) times. Zero the machine again. Within two (2) cycles the instrument shall not deviate greater than 0.02 percent units from the original zero reading;

(b) Repeatability check. Ten (10) consecutive readings on a single, well-mixed, unhomogenized milk sample shall be made for each component being tested for pay purposes. The repeatability check shall be acceptable when the comparison range of ten (10) consecutive readings is within ±04 percent units for each of these components. The sample used between the zero checks in paragraph (a) of this subsection may be used for the repeatability check;

(c) Accuracy check. A subsample from each of the control samples shall be analyzed to obtain readings for each component tested for pay purposes. These results shall not differ from the control sample by more than ±0.09 percent units for total solids and ±0.05 percent units for each other component when compared to the established values of the control samples;

(d) Hourly check. An accuracy check as established in paragraph (c) of this subsection shall be analyzed on at least one (1) sample each hour during which samples are tested for pay purposes; and

(e) Electronic instruments not meeting the established testing criteria shall not be used to test permitted producer’s samples for pay purposes. Deficiencies shall be investigated and corrective action taken. A record of any corrective action shall be maintained for at least two (2) years.

(4) Calibration requirements.

(a) Electronic instrument calibrations shall be required if:

1. The instrument is installed or significantly moved;

2. The daily performance checks fail and cannot be corrected by other means; and

3. Any part that could affect proper operation of the instrument has been replaced, rebuilt, or adjusted.

(b) A calibration shall be evaluated for accuracy:

1. At regular intervals not to exceed a thirty (30) day period; and

2. Using a minimum of eight (8) milk samples that shall cover the component ranges of samples typically analyzed with the instrument. These samples shall be in the milk fat range of two (2) to six (6) percent.

(c) Electronic instruments shall be calibrated according to the manufacturer’s instructions using milk samples with known component values as determined by a reference method approved based on accuracy. Laboratories may use approved, commercially-prepared calibration samples in lieu of preparing their own reference calibration samples.

Section 4. Wild Tests. (1) A "wild" test shall be a test result for a producer’s bulk-tank milk sample that is dissimilar to other test results for the producer during the pay period and for which the cause of the difference or differences cannot be determined.

(2) Each laboratory shall have written specifications for determining a "wild" test. Specifications for "wild" tests shall not exceed 0.50 percent units in comparing milk fat test results between or among samples for a permitted producer.

(3) "Wild" tests shall not be used for pay purposes and shall be conspicuously identified within laboratory test records.

Section 5. Check Samples. Periodically, the director may provide check samples to a licensed laboratory for test result comparisons and monitoring purposes. A licensed tester at the laboratory shall test each sample for components used for pay purposes using methods routinely utilized by the tester and approved based on accuracy. The tester's results shall be provided to the director within three (3) working days of receipt of the samples. The licensed laboratory shall be responsible for returning all check sample shipping containers and equipment to the director.

Section 6. Laboratory Records. (1) Laboratory records shall be kept in a manner consistent with 12 KAR 5:070, Section 2, and shall be retained for at least a two (2) year period.

(2) Equipment records. Records of the operation and maintenance of each electronic instrument shall include:

(a) Maintenance records;

(b) Daily performance check records; and

(c) Complete calibration records.

(3) Test records. All records of tests to be used for pay purposes shall be original and recorded as tests are conducted.

(a) Records of retests and special tests shall be conspicuously identified.

(b) A licensed tester shall be responsible for the accuracy of test records for samples he or she tests for pay purposes.

Section 7. Sample Age. A permitted producer's sample being tested for pay purposes shall be tested within seventy-two (72) hours from the time of procurement, as identified on the sample container, unless the sample is preserved with a preservative approved based on efficacy.

Section 8. Hours of Operation. A licensed laboratory that is not open during the normal business hours of Monday through Friday, 8 a.m. to 4:30 p.m. shall submit a monthly testing schedule to the director one (1) month in advance.

Section 9. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Official Methods of Analysis of AOAC International", Volume II, Chapter 33, 21st Edition, 2019; and

(b) "Standard Methods for the Examination of Dairy Products", 17th Edition, 2004.

(2) These materials may be inspected, copied or obtained, subject to copyright law, at the Division of Regulatory Services, College of Agriculture, 103 Regulatory Services Building, University of Kentucky, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m. (AES-4, CL-13, 19, 25; 1 Ky.R. 1233; eff. 7-2-75; Am. 11 Ky.R. 612; eff. 11-13-84; 15 Ky.R. 1118; eff. 11-23-88; 27 Ky.R. 1850; 2418; eff. 3-19-2001; 47 Ky.R. 741, 1252; eff. 2-9-2021.)